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Federal Communications Commission
Office of Secretary

Marlene H. Dortch, Secretary
Federal Communications Commission
Office of the Secretary
c/o Natek, Inc.
236 Massachusetts Ave, NE
Suite 110
Washington, DC 20002

Re: In the Matter of Petition to Amend the Medical Implant Communications Service (MICS) Rules to Add Inductive Telemetry at 90-110 KHz, Expand the MICS Spectrum and Make Other Technical Changes in MICS

Our Ref.: 11658-011001

Dear Ms. Dortch:

Enclosed please find the original and four copies of a Petition for Rulemaking filed on behalf of Guidant Corporation relating to the above-referenced Petition for Rulemaking. If there are any questions regarding this filing, please contact the undersigned.

Sincerely,

Terry G. Mahn

TGM/jls

Enclosures

cc (via email): Julius P. Knapp, Acting Chief, OET
Bruce A. Romano, Associate Chief, OET
Rashmi Doshi, Chief, Laboratory Division, OET
William Lane, Associate Chief, Policy and Rules Division
Joe Dichoso, Equipment Authorization Branch Chief
Martin Perrine, Senior Staff Engineer
Karen Rackley, Chief of the Technical Rules Branch
Jamison Prime, Spectrum Policy Branch Chief
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OET 08-12

Before the
Federal Communications Commission
Washington, D.C. 20554

Petition to Amend the Medical Implant Communications Service (MICS) Rules to Add Inductive Telemetry at 90-110 kHz, Expand the MICS Spectrum and Make Other Technical Changes in MICS	)))))	RM-

Petition for Rulemaking

Guidant Corporation (Guidant) hereby requests that the Office of Engineering and Technology (OET) include, in its upcoming Notice of Proposed Rulemaking on radiofrequency medical devices,[1] several changes to the Part 95 rules for the Medical Implant Communications Service (MICS). Specifically, Guidant requests that the Commission: (I) add medical implant devices that use inductive telemetry in the 90-110 kHz band; and (II) make several changes to the existing 400 MHz band, such as allocating additional spectrum, increasing the maximum channel bandwidth and transmitter power for Active Medical Implantable Devices (AIMD) and adopting alternatives to the existing frequency monitoring requirements, including the use of spread spectrum, to make more efficient use of the MICS spectrum.

Background

Guidant is a leading worldwide manufacturer of medical devices for cardiac patients. It has been manufacturing implantable devices with "communications features" since the early 1960s. Guidant heart devices include implantable pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices. Historically, these devices have used inductive coupling to communicate heart information between patients and doctors.

[1] *See* Telecommunications Reports, February 1, 2006 at 34. OET has announced that it is preparing a comprehensive review of rules involving the spectrum needs of advanced medical technologies.

Inductive coupling has been a cost effective solution for early generations of implants due to the relatively small form factor and low energy requirements of this technology. An undesired by-product of inductively-coupled implants is that they produce very low levels of radiated emissions across several frequency bands, including, in some instances, the 90-110 kHz band, which is a restricted band under Section 15.205.[2]

Guidant's next generation of implants will feature an advanced ICD design that will include an expanded memory and high-speed two-way communications. These new devices will store and download larger quantities of heart rhythm data for improved patient care. As doctors demand even higher speed delivery of increasing amounts of implant information, the need for additional spectrum will continue to grow. Moreover, as implant patient populations expand and other medical therapies move into implant arenas, spectrum availability and interference among devices will become pressing regulatory concerns. One look at today's MICS rules and it is clear that they are inadequate to meet these future demands. Thus, the spectrum allocated to MICS needs to be expanded substantially and the technical rules overhauled.

I. Inductive Medical Telemetry Applications Should be Included in MICS

Currently, there are millions of people with implants in all walks of life who depend on inductive telemetry to communicate heart rhythm data to their doctors. In the typical case, an implanted pulse generator (PG) collects real-time or stored heart data, which is communicated to a programmer-reader monitor (PRM) via handheld wand. Downloading is initiated by the PRM wand held in contact with, or very close to, the patient's chest while a pulsed magnetic field is induced at low frequency (*e.g.*, 40-50 kHz). When the PG senses the field, it responds by modulating its own magnetic field with encoded data. Implant data downloaded in this fashion can take 20 minutes or longer, depending on how much information is stored in the PG and retrieved by the PRM.

[2] The 90-110 kHz band is restricted because it is assigned for navigational use (*i.e.*, Loran C). Any unlicensed device approved under Part 15 may only emit spurious energy in a restricted band.

During the initiation[3] and downloading process, undesired radiated emissions are generated by the induction process. Typically, however, the energy levels of these emissions are 50-90 dB below the Commission's general Part 15 limits for intentional radiators and present no possible threat of harmful interference to band licensees.[4] While early implant designs generated radiated emissions at very low frequencies where few licensees exist, the demand for higher data rates (*i.e.*, less patient time under the wand) forced implant manufacturers to migrate to higher bands, including the 90-110 kHz band. Even with the new RF designs, inductive communications will continue to serve a critical backup function in the event the RF link is ever jammed. Thus, it is Guidant's view that inductive medical telemetry should be included in the Commission's Part 95 rules for MICS.

1. FCC Regulation of Inductive Telemetry Implants Should be Clarified

Prior to 1987, inductive communications devices were not subject to any Commission authorization requirements,[5] and the 90-110 kHz band was not identified as a "restricted band." Inductive medical implants that emitted in this or any other band were free of Commission regulation save for the general non-interference requirement, which applied to all unregulated devices. In 1987, the Commission began a rewrite of the Part 15 Rules[6] seeking to consolidate and simplify the regulations that applied to many types of unlicensed RF devices. Among other things, the Notice of Proposed Rulemaking (NPRM) sought a new definition of "intentional radiator" in place of the old definition for "low power communications device." At the time, low power communications devices were defined narrowly as devices which emitted electromagnetic energy by radiation only.[7]

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[3] The initiation "handshake" is important in order to assure patient security. Transmissions between PG and wand must be within six inches to guarantee that the responding implant is the intended target of PRM communication.

[4] *See* 47 C.F.R. § 15.209

[5] Under Section 15.4(b) circa 1987, inductive devices were required to avoid causing harmful interference to licensed services, but were not otherwise subject to any Commission technical standards or compliance requirements. 47 C.F.R. § 15.4(b) (1987).

[6] *See* Notice of Proposed Rulemaking, *Revision of Part 15 of the Rules Regarding the Operation of Radio Frequency Devices without an Individual License*, Docket No. 87-389, FCC 87-300 at ¶ 8, 2 FCC Rcd 6135, 6136 (rel. October 2, 1987) (hereinafter "Part 15 Rewrite").

[7] Prior to 1989, Section 15.4(f) defined a Low Power Communications device as: "...a restricted radiation device, exclusive of those employing conducted or guided radio frequency techniques, used for the transmission of signs, signals (including control signals), writing, images and sounds, or intelligence of any nature of radiation of electromagnetic energy." 47 C.F.R. § 15.4(f) (emphasis added).

The Commission's proposed definition of "intentional radiator" did not purport to expand its jurisdiction over unlicensed devices and, in any event, the NPRM gave no notice that induction devices were meant to be included in the new definition.[8] When the first Report & Order was released in 1989, however, the Commission, without explanation, changed the wording in its proposed definition of intentional radiator by removing of the words "over the air" and substituting the words "by radiation or induction."[9] No comments filed in the docket had called for such expansion of Commission jurisdiction. Thus, the new rule was implemented without prior notice or opportunity for industry comment. The net effect was to bring many types of previously unregulated devices into the Commission's equipment authorization program for the very first time.

It was also during the Part 15 Rewrite that the U.S. Coast Guard requested that the 90-110 kHz Loran C band be added to the list of "restricted" bands to protect users from possible harmful interference from unlicensed devices.[10] The Commission granted the Coast Guard's request and added the band, along with several others, to the restricted list, which now appears in Section 15.205. At the same time the Commission expand the restricted list, it made another key change in the rules that affected the kinds of emissions that would be permitted in such bands from unlicensed devices. Before 1989, an unlicensed device could generate any type of emission (*i.e.*, fundamental or spurious) in a restricted band, provided it was at a reduced level.[11] Under the new rules, however, only spurious emissions would be permitted in the restricted bands and fundamental emissions would be barred entirely. No explanation was provided by the Commission as to whether newly-regulated induction devices were also meant to be targeted by this new scheme.[12]

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[8] The NPRM defined "intentional radiators" as "devices that intentionally generate and transmit radio frequency energy over the air. Examples are walkie-talkies, garage door opener controls, security alarm devices, cordless telephones, etc."

[9] *See* First Report and Order, *Revision of Part 15 of the Rules Regarding the Operation of Radio Frequency Devices Without an Individual License*, Docket No. 87-389, FCC 89-103 at ¶ 16, 4 FCC Rcd 3493, 3495 (rel. April 18, 1989) ("Intentional Radiator. A device that intentionally generates and emits radio frequency energy by radiation or induction."). See Section 15.3(o) of the rules.

[10] See Section 15.205 of the rules.

[11] The restricted band limits, circa 1987 were 15uV/m at 3m.

[12] Arguably, induction devices generate only RF spurious (unintended) emissions.

Presumably, no one at the time thought the new restricted band rules applied to inductive implants. Had they applied, the impact would have been devastating because it would mean that if any emissions (regardless of how insignificant) fell into a restricted band, an implant could be outlawed under the new rules. Indeed, one must surely surmise that implant manufacturers, had they known that such changes were under consideration by the Commission, would have requested a grandfathering of these low power devices or, more likely, an exemption from the band restrictions that the Commission was granting to other devices at the time.[13]

Even today, it is still unclear how induction devices fit under the Commission's restricted band prohibition of Section 15.205. As noted, the rules permit only spurious emissions in these bands; but a spurious emission is defined by the Commission's rules as an emission "...outside the necessary bandwidth and the level of which may be reduced without affecting the corresponding transmission of information."[14] In an induction device, information is communicated not through the radiated energy field (which is purely a by-product of inductive coupling), but through the magnetic field which is pulsed or modulated with encoded data. While it would be expensive (and certainly useless) to suppress the radiation field, theoretically it could be done "without affecting the corresponding transmission of information."[15] Seen in this light, the radiated energy field from an inductive device squarely meets the definition of a "spurious emission" and is permitted to fall in the restricted bands. Nonetheless, given the regulatory uncertainty created by the Part 15 Rewrite, it is incumbent on the Commission to "clear the air" in a new rulemaking proceeding.[16]

2. MICS Should be Amended to Include 90-110 kHz Telemetry

At emission levels 50-90 dB below the general limits of Section 15.209, any concerns about implant interference to licensed radio (*i.e.*, Loran C) is largely academic. Indeed, the emissions

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[13] Section 15.205(d), for instance, exempts transmitters for detecting telephone markers and cable locating equipment from the 90-110 kHz restricted band prohibitions.
[14] 47 C.F.R. § 2.1(c).
[15] *See Id.*
[16] The unclear regulatory status of medical implants using inductive communications is highlighted by the March 18, 1999 grant of equipment authorization to St Jude Medical CRMD for a cardiac implant device operating at 100 kHz. Even the Commission's Laboratory staff was not aware of the virtually unpublicized changes to Part 15 made ten years before.

from inductive implants are so far below the ambient noise floor that the PRM wand cannot receive them more than 6 inches from a patient's chest. Yet, because by-product radiated emissions from some implants fall within the 90-110 kHz restricted band, unlicensed operation under Part 15 raises theoretical questions of compliance with Commission rules. One solution would be to carve out a narrow exception to the Part 15 restricted band prohibitions for medical implants. This, however, creates possibly unwanted precedent for other medical devices that might not be as acceptable to federal users as heart implants.[17] A better solution, therefore, would be to amend the MICS rules to expressly include all implants, including those that operate inductively in the 90-110 kHz band. Inasmuch as inductive links will continue to serve a critical backup function in future generations of medical implants, it makes good "regulatory sense" to include all such devices under Part 95.[18]

II. Proposed Revisions to the MICS Rules

By any measure, the MICS rules have not been a resounding success. Six years after the MICS service was established, there are only four devices on the market today, all of which are manufactured by Biotronik, Inc. and require a waiver to operate.[19] The reasons for the slow development of MICS should be clear: the spectrum allocated to MICS (3 MHz) is inadequate; the power levels are too low; the channel bandwidths are too narrow; and the rules for frequency monitoring are both costly and ineffective. These limitations have driven Guidant to consider using the 902-928 MHz band for its next generation of ICD implants. Yet, as the Commission is aware – and has made abundantly clear to Guidant – the 900 MHz band is becoming increasingly crowded and may well not be optimum, over the long run, for devices designed to provide essential medical functions. Guidant has looked into several other candidate bands for implant telemetry and found each to be lacking in some fundamental way, either technically, economically or politically. On the assumption that no band or current service can provide a

[17] Additional pressure to resolve this problem is a Petition for Waiver filed by Respironics, Inc. on October 28, 2005 (ET Docket No. 05-331). Respironics manufactures a device worn on the wrist to measure data associated with sleep disorders. This device also operates at 90-110 kHz.

[18] Inductive implants should only be governed by field strength limits. The MICS requirements for frequency monitoring, bandwidth, etc. should not apply to inductive devices.

[19] The devices (FCC IDs PG6BA0T, PG6BELOS-T, PG6LEXOS-T and PG6CYLOS) were permitted to operate without employing the frequency monitoring required under Section 95.628. Three equipment authorizations in the MICS service have also been granted to Medtronic, Inc. Apparently, these devices are not on the market.

long term solution for medical implants absent substantial regulatory reform, Guidant believes the best option lies with MICS. Therefore, with the changes to MICS recommended below, it is Guidant's view that this service still represents the best hope for future generations of medical implant patients.

1. The MICS Allocation Should be Increased by 12 MHz

The spectrum currently allocated to MICS is insufficient to support the variety of implants and data rates being demanded by doctors (and patients) in the years ahead. In a recent petition to amend the Part 95 rules, Medtronic called for an expansion of the MICS band, but only for a new short-range medical service that would operate exclusively in the 401-402 MHz and 405-406 MHz regions.[20] While it is not clear why anyone would promote a new (and rather limited) medical service when the MICS bands continue to lie fallow, the Commission should realize that the public interest requires that MICS reform be given first and highest priority.[21] In this respect, Guidant urges the Commission to add to the current MICS allocation not only the contiguous 2 MHz identified by Medtronics, but also the bands from 406 and 416 MHz.

As noted, the future demand for medical implant spectrum[22] will overwhelm MICS unless the current allocation is significantly expanded. Higher data rate devices (requiring wider bandwidths), capable of handling multiple independent sessions among co-located patients without interference, will require additional channels and thus, more spectrum. To meet the future needs of implant patients, Guidant estimates that the MICS allocation must be increased by a minimum of 12 MHz. Unless the spectrum issue is promptly addressed, advances in implant technologies will slow and patient care suffer due to band overcrowding. An inspection of the bands between 401-416 MHz reveal similar user profiles, which suggests they should be able to accommodate a secondary allocation for MICS just as the users in the 402-405 MHz

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[20] *In the Mater of Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Data Service at 401-402 and 405-406 MHz*, Petition for Rulemaking filed by Medtronic, Inc., RM-11271 (July 15, 2005).

[21] The Medtronic petition has received scant attention. In the meantime, it should be noted that other technologies such as Bluetooth, and ultra wideband (*e.g.*, Multiband OFDM) seem well-suited to transmit short-range medical data from externally located monitoring devices.

[22] It is reasonable to expect that an increase in processing power and miniaturization will lead to implants that monitor the chemical processes of therapies, neural function, the function of artificial limbs, joint replacements and more.

bands do presently. Moreover, because MICS transmissions are typically of short duration, almost always indoors and require spectrum monitoring to prevent interference to others, the primary users in these bands are assured of being unaffected by a secondary implant allocation. For these reasons, the expansion of MICS for 401-416 MHz will serve the public interest and should be carefully considered by the Commission in any upcoming rulemaking.

2. MICS Transmitter Power Levels Should be Increased

There is a growing need for implants, particularly heart implants, to communicate over greater distances than the current rules, at 25 microwatts EIRP (-16 dBm), allow. For instance, it is increasingly difficult, if not impractical, to position implant monitoring equipment near patients in operating environments when physicians and nurses require unfettered access to patients at all times. In addition, in an operating theaters, implant monitoring equipment must be located outside the "sterile field," which often means an estimated 30 feet or more between implant and reader. Furthermore, where multiple patients reside in a common areas (e.g. nursing homes, hospital wards, etc.), independent sessions with individual patients become increasingly economical and convenient as the distance between implants and programmers increases. Yet, the power permitted under MICS accommodates, at most, 6 to 8 feet of separation.

Guidant urges that the MICS rules be amended to permit transmission levels that are sufficient to communicate over the distances required to clear sterile/operating fields and to economically service multiple patients in group environments. For conventional fixed frequency MICS transmitters, this will require power levels to be increased to 0 dBm EIRP. For frequency hopping spread spectrum transmitters (see Section 4 below), which are much less prone to causing or receiving interference, Guidant urges the Commission to adopt peak power levels up to +7 dBm EIRP.[23]

A related issue inherent to MICS is the imbalance which exists in permitted power levels. The rules allow measured emissions from an implant -- *i.e.*, the downlink -- to take into account the

[23] Guidant notes that digital modulation spread spectrum transmitters are more appropriately governed by a power spectral density requirement and recommends that the Commission develop limits for MICS devices.

loss caused by tissue absorption, but do not allow for such loss when measuring the uplink.[24] The result is an asymmetric communications link between implant and programmer that can vary by as much as 8 dB. While asymmetric power levels are not an issue for one way (downlink) transmissions, for two-way communications such imbalance reduces the potential operating range by more than half. Guidant recommends that the Commission rectify the imbalance in transmission links that inherent to the MICS rules.

3. MICS Should be Channelized and Bandwidths Allowed to be Aggregated

The maximum 300 kHz channel bandwidths permitted by MICS will soon be insufficient to accommodate time-critical transmissions of heart data made possible by today's larger implant memories. Guidant's next generation implants will transmit real-time electrocardiograms and cardiac event histories from multiple patients, all within range of each other in hospital or clinic settings. Battery life is also a factor. Today's implants must last seven to nine years on a single battery which means that transmission time must also be kept to a minimum. To provide the desired levels of patient health care without causing interference, implants will need to operate on pre-designated channels and over larger bandwidths.

This can be accomplished as follows. First, conventional fixed frequency implants should be required to transmit in 300 kHz channels assigned to the MICS spectrum. Second, implants should be permitted to aggregate adjacent channels for wideband communications functions. In the proposed 15MHz allocation for MICS, Guidant believes the Commission should permit up to five channels to be aggregated. In any event, an aggregation of three channels minimum should be permitted regardless of allocation, to ensure sufficient capacity for high speed downloads. Finally, for implants that use spread spectrum techniques (i.e. frequency hopping or digital modulation), there should be no channelization requirements as these devices are inherently non-interfering to other users in the band.

[24] *See* 47 C.F.R. §§ 95.639(f)(1) and (2).

4. The Frequency Monitoring Rules Should be Reformed.

It is clear that some frequency monitoring scheme is required to avoid interference between implants and other users of the spectrum. Any workable scheme must take into account potential interference among implants as well as to and from primary band users. Guidant believes that the Commission's current frequency monitoring requirements in Section 95.628 are inadequate to address future needs and competing spectrum uses. For instance, the ten millisecond listening period, thought to be adequate six years ago, cannot reliably determine MICS spectrum availability where other users are transmitting non-continuous or duty cycled data. Guidant recommends that the rules require a listening period of at least 100 milliseconds for conventional fixed frequency transmitters.

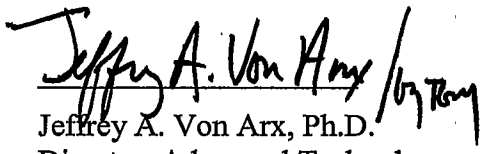
Guidant also believes the Commission should permit other types of interference avoidance technologies to be deployed in the MICS band. It should be clear that the risk of harmful interference can be greatly reduced, or eliminated, by implants that use spread spectrum techniques such as pseudorandom frequency hopping or digital modulation. Both of these dynamic interference avoidance techniques offer distinct advantages over the fixed frequency monitoring systems now required, and go hand in hand with Guidant's request for a wider MICS allocation and increased power levels. Because any interference encountered from a spread spectrum implant would be transient (and non-harmful), there should be no frequency scan, or listen before talk, requirement for implants which feature these or other types of dynamic spectrum monitoring techniques.

Finally, Guidant believes that, for fixed frequency devices, the frequency scan sensitivity levels (-96 dBm) are far too low and add unnecessary costs to implant systems and patient care. Guidant believes that the detection limits for MICS could be increased to -85 dBm peak without increasing the risk of harmful interference to other band users. Guidant urges the Commission, therefore, to adopt these higher limits.

Conclusion

For the reasons provided, Guidant respectfully requests that the Commission amend the Part 95 rules permit operation of inductive implants at 90-110 kHz, and to make the other technical changes in MICS as recommended. These revisions to the MICS rules will facilitate and improve patient health care by enabling the use of new generations of sophisticated medical implant telemetry technologies.

Respectfully Submitted,



February 21, 2006

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